UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	Hon. Patti B. Saris

UNITED STATES' CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO THE DEY DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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I. INTRODUCTION

In this Memorandum and related papers filed herewith,[1] the United States demonstrates, beyond any reasonable dispute, that the defendants, Dey, Inc., Dey L.P., Inc., and Dey, L.P. ("Dey"), reported false Average Wholesale Prices ("AWPs") and Wholesale Acquisition Costs ("WACs") to industry publishers, knowing that those fictitious prices would be used by the Medicare and Medicaid programs in determining reimbursement to health care providers nationwide. This conduct violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a) (1) and (a)(1)(B).[2]

The United States accordingly seeks partial summary judgment that (1) Dey's reported AWPs for the Subject Drugs (albuterol sulfate, ipratropium bromide and cromolyn sodium) were false for the entire time period at issue, and Dey's reported WACs for certain albuterol products were false for the time period of June 1, 1995, through December 31, 1997; (2) Dey's reporting of false prices caused providers to submit false claims to State Medicaid programs and caused the

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[1] The United States has filed a common brief that pertains to the instant case and *United States ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc.,* Civil Action No. 06-11337-PBS (D. Mass.); and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corporation, Inc., et al.*, Civil Action No. 01-12257-PBS (D. Mass.). The United States also has filed a Local Rule 56.1 Statement of Undisputed Material Facts Common to all Defendants ("US-C-SF ¶") and a Local Rule 56.1 Statement of Undisputed Material Facts in Support of the instant motion ("US-D-SF ¶").

[2] The FCA was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to this case by virtue of Section 4(f) of FERA, while Section 3729(a)(1) of the statute prior to FERA remains applicable here. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date . . . ." FERA, section 4(f).

State programs to submit false claims to the federal government for federal monies; (3) Dey's false prices for its ipratropium bromide products caused false claims to be submitted to the Medicare program;[3] and (4) Dey "knowingly" reported false prices within the meaning of the FCA. The United States further seeks summary judgment on the following Affirmative Defenses asserted by Dey: Seventh, Ninth, Thirteenth, Twenty-First, Twenty-Second, Thirty-Ninth, Forty-Ninth, Fifty-Sixth, Fifty-Seventh, Fifty-Eighth, Sixty-First, and Sixty-Fifth.[4] Dey's Answer to United States' First Amended Complaint (Master Document No. ("MD#) 5633). The United States further demonstrates that there is no merit to Dey's motion for partial summary judgment (MD# 6178, Subcategory No. ("Sub.#") 236).

II. THE UNDISPUTED FACTS

The First Amended Complaint ("FAC") alleges violations of the FCA, 31 U.S.C. § 3729, with respect to three classes of Dey drugs: albuterol sulfate, cromolyn sodium, and ipratropium bromide. All are generic inhalation therapy drugs used to treat respiratory diseases. All are covered by Medicaid. US-D-SF ¶¶ 7, 8, 12. Most are covered by Medicare, although in this motion, the United States seeks partial summary judgment with respect to Medicare claims for ipratopium bromide only. Dey sells the Subject Drugs to various classes of customers, including wholesalers, retail pharmacies, homecare pharmacies, and hospitals. US-D-SF ¶¶ 35-57; Local

[3] As detailed herein, the United States is seeking summary judgment for a subset of Medicare claims processed by one Medicare carrier, from April 1, 1997, through September 30, 2001.

[4] The basis for summary judgment on Dey's defenses of failure to mitigate, contributory negligence and comparative fault is set forth entirely in the United States' common brief. The legal basis for summary judgment regarding Dey's defenses of estoppel, waiver, and consent or ratification is also set forth in the common brief.

Rule 56.1 Statement of Undisputed Material Facts by Dey, Inc., Dey, L.P., and Dey L.P., Inc. ("Dey SOF") ¶¶ 47, 89, 93, 164.

A. Dey's Price Reporting Practices

As Dey has acknowledged, its historic practice when launching a drug has been to report its internally determined AWPs and WACs to First Data Bank ("FDB"), Medi-Span, and Red Book (the "Publishers"). US-D-SF ¶ 58. After the launch of a drug, Dey periodically reported its AWPs and WACs to the Publishers, including when there was a price change. *Id*. ¶ 59. Dey expected that the Publishers would publish the reported prices, and the Publishers did. *Id*. ¶¶ 60-61, 64, 66-71.

The undisputed evidence demonstrates that the AWPs that Dey caused to be published were inflated when the drugs were launched, and became increasingly inflated as real prices dropped and the AWPs remained unchanged. [5] The spreads have been calculated by comparing the average sales prices ("ASPs") in Dey's sales transaction data with the prices published by . US-D-SF ¶¶ 72-73. These comparisons and spreads show without doubt that the AWPs reported by Dey were unmoored from prices actually paid in the market.

The AWP-based spreads on Dey's albuterol sulfate unit dose products ranged from a low of 75.6% at the time of launch in 1992, and grew to 301% in 1998, and to 1,246% in 2007. US-D-SF ¶ 74. Dey also reported inflated WACs for these products to FDB in May of 1995, causing

[5] Addendum A to this memorandum shows some representative spreads on the Subject Drugs. The spreads are calculated consistent with the approach selected by the Court in *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 87 n.61 (D. Mass. 2007). A time-line price chart and spread summary for each NDC is appended to the Declaration of Simon D. Platt (Exhibit 19 to the Declaration of George B. Henderson, II).

FDB to publish inflated WACs from June 1, 1995, to December 31, 1997, with WAC spreads ranging from 150% to 237%, before the prices were reduced. US-D-SF ¶ 80.[6]

Dey's AWPs for its other albuterol sulfate products (the metered dose inhaler (MDI), the MDI Refill, and the albuterol sulfate multi-dose solution), its cromolyn sodium, and the ipratropium bromide were similarly inflated. For example, the spreads on the albuterol sulfate multi-dose solution (NDC# 49502-0196-20 and 49502-0105-01) ranged from 160% in 1996 to 364% in 2003. *Id.* ¶ 77. The spreads on the cromolyn products were modest (42%) when the products were launched in 1994, but grew to 125% in 1998 and 424% in 2004. *Id.* ¶ 78. The spreads on ipratropium bromide were 105% in the first year of sales, and grew to 1,699% in 2003. *Id.* ¶ 79.

B. The Impact of Dey's False AWPs and WACs on the Medicaid Program

The reimbursement methodology employed by virtually every State Medicaid program, throughout the relevant time period, has included a "lower of" component. US-C-SF ¶ 29. The vast majority of States use a methodology by which drug reimbursement is paid at the lower of (1) Estimated Acquisition Cost ("EAC"), (2) the Usual & Customary Charge ("U&C"), and (3) any Federal Upper Limit ("FUL") established pursuant to 42 C.F.R. § 447.332. US-C-SF ¶ 29. A majority of States also have developed Maximum Allowable Cost ("MAC") programs which establish upper payment limits similar to the federal FULs and which are included as a fourth component to the "lower of" methodology. US-C-SF ¶ 32. Some States also use the

[6] The Complaint alleges that Dey reported falsely inflated WACs for its other Subject Drugs. However, the United States is not seeking summary judgment as to WAC reporting on those other drugs.

"DOJ Prices" as an additional element to the "lower of" methodology.[7] *Id.* ¶ 33. All States use the AWPs and/or WACs reported by the Publishers to determine their EAC, with the great majority using AWPs published by FDB. *Id.* ¶ 30, 34.

Because States' reimbursement methodologies apply AWPs and/or WACs in determining which of the enumerated price alternatives is the "the lower," there is no genuine issue that inflated AWPs and/or WACs are materially ***and*** causally connected to the false claims to the government for the Subject Drugs.

C. The Impact of Dey's False AWPs For Ipratropium Bromide on the Medicare Program

As set forth in the United States' common brief and common statement of facts, since the early 1990's, Medicare Part B has typically paid for covered drugs using AWP prices published in the Red Book. US-C-SF ¶ 2. Ipratropium bromide is a respiratory drug used with durable medical equipment such as nebulizers. US-C-SF ¶¶ 15-16. The four carriers who paid the Medicare Part B claims at issue here – known as Durable Medical Equipment Regional Carriers ("DMERCs") – processed claims for ipratropium using Healthcare Common Procedure Coding System ("HCPCS") codes. US-C-SF ¶¶ 4, 6. For the time period at issue in this motion, the codes were K0518 (April 1, 1997, through 1999), and J7644 (January 1, 2000, forward). US-D-SF ¶ 201. The Medicare allowed amount was the lower of the fee calculated by the DMERC or the amount submitted by the provider in the claim form. US-C-SF ¶¶ 11-13. The United States seeks partial summary judgment as to claims processed by the DMERC for Region D, CIGNA Government Services ("CIGNA"), from April 1, 1997, through September 30, 2001.

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[7]The "DOJ Price" refers to prices provided in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units ("NAMFCU"), and published by FDB. US-C-SF ¶ 33.

CIGNA (like the other DMERCs) determined the allowed fee for ipratropium on a quarterly basis using the AWPs published in the Red Book. US-C-SF ¶¶ 15-16. From 1996 through 1997, CIGNA followed HCFA instructions and calculated the allowable amount as the median AWP of the generic forms of the drug, recording its determinations in an "array" usually prepared quarterly. *Id.* ¶ 16. Effective January 1, 1998, following passage of the Balanced Budget Act of 1997, CIGNA followed new instructions and calculated the allowable fee as 95% of the lower of the median AWP of the generic forms of the drug or the AWP of the lowest priced brand name drug. US-D-SF ¶ 207.

An examination of the Medicare claims processed by CIGNA demonstrates that during this period, 910,835 claims for ipratropium bromide were paid using the allowed amounts that were based in part on Dey's AWPs. *Id.* ¶ 218.[8] Further, an examination of the CIGNA arrays shows with mathematical precision that if the AWPs for Dey's ipratropium products had been lower by just one percent, the allowed amounts for Medicare claims processed by CIGNA from the second quarter of 1997 through the third quarter of 2001 would have been lower.[9] *Id.* ¶ 216.

D. Dey's Knowledge of Its False Prices and Their Use by the Medicaid and Medicare Programs

1. *Dey's Launch of Albuterol Sulfate Unit Dose*

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[8]Medicare reimbursed these allowed amounts for any drug within the HCPCS code, whether manufactured by Dey or not. US-C-SF ¶¶ 4, 11-13.

[9] For quarters after 2001 Q3, the allowed amount is lower if the AWPs for both the Dey and Roxane ipratropium products are reduced by one percent or more. In this motion, however, the United States does not seek summary judgment based on its "joint impact" theory. In light of the joint harm caused to the United States by Dey and Roxane's false AWPs for this drug, the United States does intend to move to consolidate the two cases for trial and proceed on a joint theory of liability and damages with respect to ipratropium. US-D-SF ¶ 219.

Dey's launch of its Albuterol Sulfate Unit Dose products in March 1992 illustrates the pattern of falsity and demonstrates the motivation behind Dey's price reporting conduct for all of the Subject Drugs. Dey was the first generic entrant to this particular market and enjoyed a six-month period of protection from other generic competition. US-D-SF ¶ 9. Before the launch of this drug, Robert Mozak, Dey's Vice President of Sales and Marketing, circulated an "Albuterol Pricing Strategies" memorandum to the company's top officers, including its President, stating that a strategic "objective" was to "provide an incentive to retail and chain pharmacies to purchase Dey's albuterol unit dose by increasing the spread on Medicare/Medicaid reimbursements." Two prominent "strategies" were to "1) Increase the spread to retail/homecare accounts by lowering acquisition cost more than AWP," and "2) [establish a] pharmacy chain bid range: $23.95 - $26.50 (avg. $25.95) [that] will increase spread for retail and provide Dey with highest profit." US-D-SF ¶ 81.

Around this time, Mr. Mozak instructed Dey Marketing Manager Helen Burnham (later Selenati) to contact FDB and find out what would be the highest AWP that Dey could report and still ensure that the drug would be classified by FDB as a generic. Ms. Burnham contacted Ed Edelstein at FDB who, according to Ms. Burnham, told her that in order to ensure a drug's status as a generic, the AWP had to be at least ten percent below the AWP of the brand version. US-D-SF ¶ 82. Ms. Burnham prepared a marketing plan for the albuterol product, dated February 1992, which incorporated the same language from Mr. Mozak's memorandum quoted above. *Id.* ¶ 83. Dey subsequently reported an AWP of $32.25 to FDB, which was about ten percent below that of the brand. US-D-SF ¶ 84. In 1994, Dey reduced its AWP to $30.25 (the reasons are unclear), and thereafter never changed it. *Id.* ¶¶ 84-85.

In 1993 and 1994, employees in Dey's Sales and Marketing department gathered extensive information about reimbursement under the Medicare Part B program and each State's Medicaid program. US-D-SF ¶¶ 89-90. Dey continued gathering such information in later years. *Id*. ¶ 91.

2. *Dey's Launch of Cromolyn Sodium*

In preparation for Dey's launch of cromolyn sodium, Mr. Mozak prepared an October 15, 1993, memorandum to the Chief Financial Officer, Ms. Marrs, and the new President, Charles Rice, setting forth a recommended pricing structure for cromolyn. This pricing structure, among other things, quantified the "spread to homecare pharmacists." US-D-SF ¶ 93. In December 1993, Robert Ellis, who worked under Mr. Mozak, prepared a launch plan for cromolyn that included an analysis of the profit that a homecare pharmacist would make from Medicare reimbursement. It also set forth "pricing objectives," one of which was to "provide an incentive to retail/chain providers to purchase Dey's cromolyn by increasing the spread on Medicare/Medicaid reimbursements." It also set forth a pricing structure analysis similar to the one recommended in Mr. Mozak's memorandum of October 15, 1993. *Id*. ¶ 94. Mr. Ellis testified that the recommended pricing for cromolyn was based on his understanding of the company's past experience with albuterol. *Id*. ¶ 95.

Shortly thereafter, Mr. Ellis prepared an "Abridged Marketing Plan" dated January 1, 1994, which contained the same "pricing objectives" language quoted above. Dey's President, Mr. Rice, received it. *Id*. ¶¶ 96. When questioned about this document, Mr. Rice testified:

> Q. And was the intent there to arrange a spread on Medicare/Medicaid reimbursement on Dey's generic cromolyn that

> was -- that was a greater spread than what the pharmacy would enjoy if they bought the brand?
> A. I believe that was probably what Mr. Ellis intended, yes.
> Q. And that was the intention of -- of Dey in terms of its pricing strategy whenever it launched a generic drug, correct?
> A. That's correct.
> Q. Build in a bigger spread than the pharmacist or provider could make if it -- than if -- than if it bought the brand drug?
> A. That's correct.

Id. ¶ 98. Dey launched the cromolyn product in April or May 1994. *Id*. ¶ 99.

During 1994 and 1995, Dey trained its sales force to market the spread. Newly hired sales representatives were taught how to compare the spread on Dey's products to the spread on a competitor's product. US-D-SF ¶¶ 102-103. At a January 1994 annual National Sales Meeting, Dey sales manager Ross Uhl gave a presentation that explained the details of how Medicare and Medicaid reimbursement worked, and how pharmacists profited from the spread between their acquisition costs and AWP-based reimbursement. *Id*. ¶¶ 105-107.

At the next annual National Sales Meeting in January 1995, Mr. Uhl and Dey Marketing manager Debi Codute gave a workshop presentation on marketing the spread. The workshop included discussion on how to compare the spread and profit on Dey's unit dose albuterol against the multi-dose albuterol products marketed by Schering and Warrick. The handouts at the workshop included worksheets for comparing the reimbursement and profit on Dey's albuterol unit dose product with the reimbursement and profit on the competitor's multi-dose product. *Id*. ¶ 108-116. These worksheets were later consolidated into a single "Reimbursement Comparison Worksheet" that was formally approved by Dey's President, its CFO, and Mr. Mozak. *Id*. ¶ 120-121. The "Reimbursement Comparison Worksheet" was distributed to Dey's sales force by a

Memorandum dated April 5, 1995, which stated, "The worksheet is more impactful when you work through it with a customer . . . ." *Id.* ¶ 119.

3. *Dey Reported Inflated WACs to FDB In Order to Increase Reimbursement In WAC States*

In mid-1995, Dey Marketing Manager Helen Burnham learned that Dey had lost the business of a Florida customer because the WAC spread on the albuterol product of a competitor, Warrick, was greater than the spread on Dey's product. US-D-SF ¶¶ 122. Florida's Medicaid program at the time reimbursed for drugs based in part on WAC, and Florida used the FDB Blue Book. US-D-SF ¶¶ 123. Ms. Burnham wrote a memorandum dated May 30, 1995, to Dey's sales force in which she identified the five states using WAC and stated that Dey had reported to the publishers new and higher WACs for its albuterol unit dose products. The memorandum stated, "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement." US-D-SF ¶ 124. The inflated WACs were published by FDB and remained in effect until Dey lowered them effective January 1, 1998. *Id.* ¶¶ 127-128.

4. *Dey's Launch of Ipratropium Bromide*

Dey launched its ipratropium products in January 1997. In preparation for the launch, Dey prepared a marketing plan that followed the same price-setting pattern that Dey used for its earlier launches. The marketing plan set forth a "Pricing Guidelines" table that set Dey's AWP at 10% below the AWP of the brand product, Atrovent (manufactured by Boehringer Ingelheim Corp.), and compared Dey's prices to Roxane's prices, as well as the Atrovent prices. *Id.* ¶¶ 136-

137. The plan set forth marketing strategies and tactics that included "Set price and AWP to enhance sales while maximizing customer loyalty." *Id.* ¶ 139. Dey set the AWP for its ipratropium package of 25s (NDC #49502-0685-03) at $44.10, which was 10% below the brand AWP. *Id.* ¶¶ 140, 142. In 1997, Dey's average indirect sales price to the pharmacy class of trade was $19.21, representing a spread of 129%. By the second half of 2003, prices had dropped to the point where the spread was 710%. US-D-SF ¶ 143.

The record is replete with evidence that Dey sales representatives actively marketed the spread to pharmacy customers during the 1990's. See US-D-SF ¶¶ 152-157. In 1997, the company was served with state and federal subpoenas that initiated lengthy investigations leading to law suits, including the present one. *Id.* ¶¶ 160-161. Affirmative marketing of the spread by Dey appears to have diminished. But by the late 1990's, many major wholesalers promoted computer software programs or on-line purchasing sites that allowed pharmacy purchasers to compute and compare spreads among different generic products. US-D-SF ¶¶ 158.

III. ARGUMENT

A. The Court Should Enter Partial Summary Judgment as to the Falsity of Dey's AWPs for the Subject Drugs and Dey's WACs for Its Albuterol Sulfate Unit Dose Products

The United States seeks partial summary judgment as to falsity under the FCA with respect to Dey's AWPs for all of the Subject Drugs for the entire time period set forth in the FAC, and as to Dey's WACs for its albuterol sulfate unit dose products, for the period June 1, 1995, through December 31, 1997. There is no reasonable dispute that Dey's AWPs lack a meaningful relationship to prices generally and currently paid in the market, and that Dey's

albuterol unit dose WAC did not comport with even Dey's definition of WAC. As Dey's defenses lack merit, partial summary judgment is appropriate.

1. Dey's AWPs for the Subject Drugs and Dey's WACs for Its Albuterol Sulfate Unit Dose Products Are Objectively False

Based on the plain meaning definition of AWP adopted in this matter,[10] this Court has consistently held that AWP prices that have no relationship with the actual prices paid by the defendant's customers are false. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 103, 105-08; *In re Pharm. Indus. Average Wholesale Price Litig*, 520 F. Supp. 2d 267, 270 (D. Mass 2008). The Court recently reached a similar conclusion as to WAC:

> Knowing that WAC was used to calculate EAC, and that EAC was meant to estimate what pharmacies actually pay for drugs, a jury could certainly conclude that the defendants knew or were deliberately ignorant of the fact that they were not meant to report a mere list price, a price set by manufacturers and listed at the top of invoices but almost never paid by wholesalers, but were instead meant to report a price suitable for such estimation, that is, a *real price*.

Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 154 (D. Mass. 2008) ("*Mylan Labs"*).

Tellingly absent from Dey's brief or statement of facts is any claim that its reported AWPs for the Subject Drugs were truthful. While Dey argues that its WACs represent "actual prices" (Dey SJ Br. at 16), Dey effectively admits that it manipulated WACs for its albuterol unit dose for some time period. Dey SJ Br. at 16, n.8. Consistent with its actual conduct, an internal Dey memorandum states, "WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement." US-D-SF ¶¶ 124. After learning it was under investigation for pricing fraud, Dey sought to cover its tracks by sending form letters to

[10] *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 277, 287 (D. Mass. 2006).

State Medicaid agencies announcing that its AWP was not a price "actually charged or paid in the market place" and that Dey's WAC was its "undiscounted price to wholesalers." *See* Response of the United States of America to Dey Defendants' Statement of Undisputed Material Facts in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment ("US Response to Dey SOF") ¶¶ 152-153. Far from being exculpatory, as Dey seeks to portray them, these letters are uncontested admissions of the falsity of Dey's reported prices.[11]

The price comparison summaries presented by the United States' expert, based on Dey's actual sales transaction data and prices published by FDB, show beyond any reasonable doubt, let alone by a preponderance of the evidence, that Dey's AWPs were substantially higher than the prices generally and currently paid in the market for Dey's products. US-D-SF ¶¶ 72-80; *see* Addendum. The information submitted by Dey's own experts confirm this. *See, e.g.,* Decl. of Lauren J. Stiroh, Figures A - K. Furthermore, despite Dey's assertions regarding its WACs, there is clear evidence that for at least one particular time period, Dey's WACs did not represent, as the Court says, "a real price."

2. None of the Evidence Cited by Dey Demonstrates Government Approval of Dey's False Price Reporting

As noted in the United States' Common Brief and recognized by the Court, the majority view is that a determination of falsity should be made independent of any purported knowledge by the government. Even if such knowledge is taken into account, however, it is only relevant to

[11]Of course, the letters did not contain any information about what Dey's real prices actually were. Not surprisingly then, even when State Medicaid officials acknowledged they might have received one or more of such letters, they were unanimous in the view that the letters were neither clear nor helpful, and that there wasn't anything they could do with a letter that addressed a handful of NDCs and had no information that could practically be programmed into the State's computerized claims processing system. US Response to Dey SOF ¶¶ 148, 150.

the extent there has been *approval* by the government of the conduct at issue. As this Court correctly noted, evidence of government knowledge concerning an issue "does not support an across-the-board government knowledge defense [where] there is no evidence of government sanction." *Mylan Labs.*, 608 F. Supp. 2d at 151. Furthermore, the case law consistently speaks in terms of *specific* approval of the *specific* conduct engaged in by the defendant. To hold otherwise would give defendants *carte blanche* to engage in ongoing schemes by arguing that the government's failure to fix the problem evidenced approval of the ongoing conduct. "[O]penness and honesty are required if government healthcare programs are "not to be turned into a cat and mouse game in which clever providers could, with impunity, practice fraud on the government." *United States v. Calhoon*, 97 F.3d 518, 529 (11th Cir. 1996).

Dey does not even attempt to argue -- likely because there is no evidence to support the contention -- that the United States government approved of Dey's false pricing. Instead, Dey focuses solely on government knowledge, arguing that the government had sufficient knowledge of Dey's prices and price reporting conduct to defeat a finding of falsity under the FCA. That contention is simply wrong. Dey's motion for partial summary judgment should be rejected on that basis alone because it fails to present evidence that Dey informed the government of the underlying facts and that the government approved its conduct.

Rulings by this Court and others on this issue have set a high standard for the type of knowledge required under the FCA, to ensure that if government officials do approve a defendant's actions, the approval is made with full knowledge of the facts of the claims. *See, e.g.*, *Mylan Labs*., 608 F. Supp. 2d at 148-50 (observing, *inter alia*, that there was no evidence "the Commonwealth knew that the spreads for drugs were almost frequently greater than 50 percent,

consistently in the hundreds, and frequently in the thousands"). Here, the collective information cited by Dey would not have enabled a government official to knowingly approve Dey's reporting of false prices, and there is no evidence that any government official ever did.

Dey initially points to its reporting of WACs as serving to notify the government that its AWPs were inflated. Dey SJ Br. at 16. Dey contends that the government should have analyzed Dey's WACs and then figured out that Dey's real prices were declining, thereby rendering its AWPs false. Tellingly, in the case law regarding government knowledge, the government is not required to piece together the facts as they are selectively disclosed by a defendant. *See Mylan Labs.*, 608 F. Supp. 2d at 150, 152 (defendants can't succeed on government knowledge defense where there was no evidence they ever "disclosed the actual underlying facts,"and "even if you didn't need Einsteinian quantitative skills to discover the fraud," state government's failure to do so was not tantamount to knowledge and approval). Purporting to tell the truth on one hand, while trumpeting a lie on the other, does not qualify as full disclosure.

Dey then contends that its reporting of average manufacturer prices ("AMPs") served to notify the government of the true facts. Dey SJ Br. at 17. This Court already rejected this assertion in the context of Medicaid, holding that the state's failure to reimburse based on AMPs "does not equate to government knowledge or approval." *Id.* The ruling applies with equal force to Medicare, particularly since AMPs are reported only in the context of the Medicaid rebate program. Dey's argument also ignores that, by statute, AMPs were required to be kept confidential. The Medicaid Drug Rebate Program, created by the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), expressly requires that AMPs provided to CMS be kept confidential and not be disclosed by CMS *except for the purpose of carrying out the*

purposes of the rebate program. 42 U.S.C. § 1396r-8(b)(3)(D) (emphasis added). Indeed, that limitation was incorporated into the specific rebate agreements entered into between Dey and CMS. US-C-SF ¶ 101. In light of the statutory restraint, HHS concluded that the data could not be used for any purpose other than the rebate program. *Id*. ¶ 103. CMS has publicly and consistently reiterated this position, and Dey offers no evidence that CMS ever used the AMPs for any purpose other than administering the Medicaid rebate program. *Id*. ¶¶ 107-114. In any event, as with Dey's WACs, giving the government one piece of the puzzle hardly qualifies as full disclosure of the specific, underlying facts.

Dey then points to Federal Supply Schedule pricing information. Dey SJ Br. at 17. As one CMS witness explained, however, such comparisons were not useful because CMS, unlike the Department of Veterans Affairs ("VA"), was not purchasing drugs directly from manufacturers, nor did Medicare (or presumably Medicaid) providers purchases drugs in the volumes that the VA did. US-C-SF ¶ 14. Thus, knowing that the VA purchased drugs for less did not automatically alert HHS that Dey's AWPs and WACs were phony.

Dey also argues that various OIG reports showing awareness of spreads for albuterol, cromolyn and ipratropium bromide translates into the required knowledge. Dey SJ Br. at 18. Dey points to scattered invoices from its customers in OIG working files as proof of government knowledge. This is hardly the full-scale disclosure mandated by the case law. The more accurate conclusion to draw from the government reports and accumulated investigative knowledge is clear *disapproval* of the conduct at issue (perhaps most obviously illustrated by the government's Complaints-in-Intervention in these cases). As this Court previously noted, for example, OIG's Pharmaceutical Guidelines released in 2003 "defeat any notion that the federal government's

failure to change the AWP pricing benchmark signaled acquiescence in spread-marketing or the reporting of mega-spreads." *In re Pharm. Indus. Average Wholesale Price Litig*, 491 F. Supp. 2d at 95.

Dey also points to disclosures by relator regarding pricing discrepancies and the government's own investigation that led to the filing of this FCA suit against Dey. Dey SJ Br. at 21, 23. The Court already rejected this same argument in the Massachusetts case, holding that disclosures by relator do "not support an across-the-board government knowledge defense because there is no evidence of government sanction. To the contrary, the purpose of the meeting was to alert government officials to possible fraud. That the government responded lethargically to the knowledge of fraud does not translate into approval." *Mylan Labs.*, 608 F. Supp. 2d at 151.

Dey cites the publication of alternative prices for albuterol in 2000 by the Department of Justice and the National Association of Medicaid Fraud Control Units, and the continued use of AWPs and WACS for reimbursement as further support for absolving Dey of liability for its false pricing. The continued use of the current reimbursement system, however, does not reflect approval of Dey's conduct, but rather the need for accurate pricing data on a consistently updated and automated basis, something the 2000 prices were not. *See* US-D-SF ¶ 18; US Response to Dey SOF ¶ 200.

Finally, Dey argues that its letters to State Medicaid agencies, written after Dey learned it was under investigation by the government for pricing fraud, constitute disclosure of the true facts here. Dey SJ Br. at 22. In the letters, Dey contends that its AWPs are not actual prices and that its WACs are an undiscounted price to wholesalers. As previously noted, since Dey did not

disclose what its actual prices were, State agencies had no way of knowing exactly how much they were overpaying for Dey's drugs. Defendants who have successfully argued government approval have been able to demonstrate full disclosure to the government such that the government could make an informed choice regarding the claims at issue. Dey's letters fall woefully short, as evidenced by deposition testimony from the very State agencies who were purportedly "informed" by the letters. Delaware's 30(b)(6) designee, for example, was not positive she had received the letter shown her by Dey's counsel, but her testimony established that whether she received it or not was of no moment:

> Q. After reading this, do you understand why Dey is changing the AWP -- the prices that are the subject of this letter?
> A. No.
> Q. Without knowing the actual prices for the products listed in Dey Exhibit 616, is the information in this letter useful to the Delaware Pharmacy Benefits Program?
> MR. CYR: Objection.
> MS. RAMSEY: Objection.
> THE WITNESS: No, it's not useful.
> BY MS. HEALY SMITH:
> Q. Could you make changes to the reimbursement methodology based on the information in this letter?
> A. No.
> Q. Is there anything you could do with the information in this letter?
> MS. RAMSEY: Objection.
> MR. CYR: Objection.
> THE WITNESS: Not with the information.

US Response to Dey SOF ¶ 150. Numerous other State Medicaid officials testified that the letters were useless because their reimbursement methodology depended upon the AWPs and WACs reported by Dey and other manufacturers to the pricing compendia. *Id*. Dey itself

concedes that no State Medicaid agency ever contacted Dey in response to the letters. Dey SOF ¶ 155. Moreover, Dey has been sued by numerous States seeking to recover losses caused by Dey's pricing fraud – hardly a sign of government approval of Dey's conduct.

In sum, in order to prevail on its claim that the government had extensive enough knowledge to negate falsity, Dey must demonstrate that it disclosed the actual facts to the government which then specifically approved Dey's reporting of false prices to the Publishers. Dey does not and cannot allege that it made any such disclosure or received any such approval, and the government vigorously contends otherwise. The United States, therefore, can establish falsity for claims for all the Subject Drugs.

B. The United States Is Entitled to Partial Summary Judgment on Dey's Affirmative Defenses Based on Government Knowledge

The United States is also entitled to summary judgment on Dey's affirmative defenses that rest on government knowledge. The affirmative defenses at issue here, for which the same body of evidence is required, are as follows: Seventh (good faith), Ninth (estoppel and waiver), Thirteenth (no falsity), Twenty-Second (consent and ratification), Thirty-Ninth (consent), Fifty-Sixth (estoppel), Fifty-Eighth (ratification), Sixty-First (consent and/or ratification), and Sixty-Fifth (government knowledge). Furthermore, as set forth in the United States' Common Brief, many of these defenses fail as a matter of law when asserted in response to an FCA action brought by the United States.

C. The United States Is Entitled to Partial Summary Judgment Regarding Materiality and Causation for False Claims to the Medicaid Program

There is sufficient evidence to find materiality and causation under the FCA based on Dey's false AWPs for the Subject Drugs, and Dey's false WACs for its albuterol sulfate unit

dose drugs. This Court has held that "[w]hether a false statement is material depends on whether it 'has a natural tendency to influence agency action or is capable of influencing agency action.'" *United States v. President & Fellows of Harvard College*, 323 F. Supp. 2d. 151, 181-82 (D. Mass. 2007)(citing *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F. 3d 908, 914 (4th Cir. 2003) (parenthetical omitted).[12] There is no dispute that the vast majority of States used a reimbursement methodology that relied on Dey's reported AWPs,[13] as did the Medicare program. The United States has set forth those methodologies on a state by state basis in its Common Rule 56.1 Statement of Facts, and further demonstrated that the States actually implemented the reimbursement formulas in their electronic claims processing systems by downloading AWPs from the pricing compendia. US-C-SF ¶34. Since the false conduct and statements affected government drug payment levels, they clearly had the natural tendency to influence – or were capable of influencing – the payment of government money for Dey's products. Thus, the falsity of the claims to Medicaid was material under 31 U.S.C. § 3729(a)(1), and the reported prices were false statements material to false or fraudulent claims to Medicaid under 31 U.S.C. § 3729(a)(1)(B).

As to causation, which is also explained in the United States' common brief, a defendant is liable under section 3729(a)(1) of the FCA when it causes to be presented a false claim for

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[12] As part of FERA, Congress codified this interpretation and described materiality as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

[13] The United States will not seek single FCA damages in those limited instances, if any, where a State would not have applied EAC to determine reimbursement, no matter what the defendant reported. This is different from the more common situation where a State paid on a basis other than EAC, but would have paid based on EAC had the defendant reported truthful prices.

payment. As this Court recently noted, the FCA "attaches 'liability upon *presentment* of a false or fraudulent claim, rather than *actual payment* on that claim.'" *Mylan Labs.*, 608 F. Supp. 2d at 147, quoting *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F. 3d 428, 445-46 (6th Cir. 2005). The test for causation directly applicable to the facts at hand was set forth by the Court in *United States ex rel. Franklin v. Parke-Davis*, Civ. No. 96-1165-PBS, 2003 WL 22048255 (D. Mass. Aug. 22, 2003): first, was the defendant's conduct a "substantial factor" in causing the presentation of false claims to the Medicaid program; and second, was the submission of false Medicaid claims by pharmacists a foreseeable consequence of the defendant manufacturer's conduct. Here, by reporting false prices to the compendia used by the Medicare and Medicaid programs to estimate acquisition costs, defendants caused providers' submitted claims for Medicare or Medicaid reimbursement on Dey's drugs to be false or fraudulent. This Court has already determined that the reporting of prices not reflective of actual transaction prices –conduct not disputed by defendants – is sufficient to cause the presentment of inflated provider claims where reimbursement is calculated based on those prices. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 175 (D. Mass. 2007).

Here, the United States has demonstrated that (1) Dey reported false AWPs to the compendia for the Subject Drugs and false WACs as stated above; (2) claims for reimbursement for Dey's Subject Drugs were submitted to State Medicaid programs; and (3) the majority of States used Dey's false AWPs to estimate acquisition cost, while others used Dey's false WACs. Causation under 31 U.S.C. § 3729(a)(1) is therefore established.

D. The United States Is Entitled to Partial Summary Judgment on Materiality and Causation for False Claims to the Medicare Program for Dey's Ipratropium Bromide Products

The United States seeks partial summary judgment as to materiality and causation for false claims to the Medicare program processed by CIGNA (the Region D DMERC), from April 1, 1997, through September 30, 2001, caused by Dey's false AWPs for ipratropium bromide. Similar to the Medicaid program, the Medicare program relied upon the false AWPs reported to pricing compendia to set reimbursement rates. From 1992 through December 31, 1997, the DMERCs paid for Part B covered multiple-source drugs based on the lower of the provider's billed charge or the median AWP of the generic forms of the drug. US-C-SF ¶ 11. From January 1, 1998, through December 31, 2003, the DMERCs paid for Part B covered multiple-source drugs based on (a) the amount submitted by the provider on the claim, or (b) 95 percent of the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest AWP of the brand name forms of the drug or biological. US-C-SF ¶¶ 12-13. CIGNA (like the other DMERCs) determined the allowed fee for ipratropium on a quarterly basis using the AWPs published in the Red Book, including Dey's AWPs. *Id.* ¶ 16; US-D-SF ¶ 204. As explained in the United States' common brief, that fact alone establishes materiality under the FCA.

Causation is also established here because Dey's conduct was a "substantial factor" in causing the presentation of false claims to the Medicare program, and the submission of false Medicare claims by pharmacists was a foreseeable consequence of Dey's conduct. CIGNA paid on behalf of Medicare many claims for reimbursement for ipratropium bromide based on a

median average wholesale price that was arrived at based on Dey's reported AWP. US-D-SF ¶¶ 212, 214-15, 218, 220.

E. Partial Summary Judgment Is Appropriate to Establish that Dey "Knowingly" Made False Statements and Caused the Submission of False Claims to the Medicaid and Medicare Programs

For purposes of the FCA, "knowledge" that the statement or document was false or fraudulent means that the defendant:

1. had actual knowledge that the information was false;

2. acted in deliberate ignorance of the truth or falsity of the information; or

3. acted in reckless disregard of the truth or falsity of the information.

No specific intent to defraud is required. 31 U.S.C. § 3729(b); *United States ex rel. Loughren v. UnumProvident Corp.*, Civ. No. 03-11699-PBS, 2008 WL 4280133 at *3 (D. Mass. Sept. 15, 2008). Knowledge may be established on summary judgment. *See, e.g.*, *United States ex rel. Longhi v. Lithium Power Techs., Inc*., 2009 WL 1959259 (5th Cir. 2009) (granting summary judgment to government on scienter in FCA case); *Harvard*, 323 F. Supp. 2d. at 190 (granting summary judgment to government on defendant's knowledge under the FCA).

Based on undisputed evidence, Dey knowingly submitted false statements and caused the submission of false or fraudulent claims. Dey knew that its reported AWPs and WACs as specified above bore little to no relation to its actual transaction prices. Dey also knew that Medicare and many State Medicaid programs utilized AWPs in setting reimbursement, while other Medicaid programs used WACs. US-D-SF ¶¶ 89-92. Dey explicitly set its prices in order to create a spread that would entice customers. To that end, Dey regularly included information about Medicare and Medicaid reimbursement in marketing documents that were used by its sales

force or provided to customers, such as the "Reimbursement Comparison Worksheet." *Id.* ¶¶ 90, 118-121. Dey officials acknowledged that Dey set its AWPs and WACs with an eye toward increasing reimbursement for its products. *Id.* ¶¶ 81, 94, 98.

Finally, Dey cannot point to any evidence of government knowledge that has any bearing on its scienter either before or after 1997 - the year Dey identifies as the start of its government knowledge defense. As explained above, Dey cannot demonstrate that either HHS or any State Medicaid agency approved its submission of false pricing information and the resultant false claims. *Id.* ¶¶ 178-79. Even if Dey could point to any such evidence, Dey admittedly did not take such information into account in deciding, at the time, to report false prices. *Id.* ¶¶ 180-89, 197-99. Notwithstanding the form letters Dey sent to State Medicaid agencies after learning it was under investigation, no Dey employee actually testified that the company relied (whether reasonably or not) on the lack of a response to the letters as a signal of approval of Dey's price reporting conduct. As a result, Dey's defenses based on government knowledge, purported approval, consent, etc., must also fail.

F. Dey Is Not Entitled to Summary Judgment on Damages

As set forth in the United States' Common Brief, Dey's arguments regarding the basis for the payment amount of a claim are properly considered in the context of damages. Even here, however, the arguments fail both legally and factually.

Dey first argues that extrapolation by the United States' damages expert, Professor Mark Duggan, Ph.D, somehow indicates that claims data does not even exist for certain States or significant time periods. Nothing could be farther from the truth. Dr. Duggan used a combination of State and federal data for all States in calculating damages. He used State-

supplied claims data for 14 States, which represents 63 percent of all claims for Dey's Subject Drugs. US-C-SF ¶ 129. The federal data used by Dr. Duggan also clearly shows reimbursement by State Medicaid programs for the Subject Drugs by NDC. The federal claims data is based on claims data submitted by the States to CMS. Thus, for States or time periods in which he did not have claims data provided by the State itself, he had data provided by the States to CMS. *Id.* ¶ 116.

Dey then argues that extrapolation cannot even be used in an FCA case, completely ignoring this Court's recent conclusion in an FCA case that "extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate." *United States ex rel. Loughren v. UnumProvident Corp*., 604 F. Supp. 2d 259, 261 (D. Mass. 2009). Here, Dr. Duggan's approach was very straightforward. Based on those states for which Dr. Duggan had direct state claims data (14 states for Dey), he calculated two ratios for each NDC-Quarter: 1) the "fraudulent claims percentage" (i.e., the percentage of claims for which there was a positive difference between what the government paid and what it would have paid if the defendant had reported their actual prices), and 2) the "fraudulent dollars percentage" (i.e., the average ratio of the difference to the amount of Medicaid spending on all claims). US-C-SF ¶¶ 118, 156. In other words, Dr. Duggan calculated the percentage of claims that were fraudulent and the percentage of money overpaid per claim. These 14 states constituted between [63-68%] of the total Medicaid spending for the defendants' drugs. *Id.* ¶ 119. To estimate the Medicaid damages for the remaining Medicaid claims and spending, Dr. Duggan calculated the averages of the "fraudulent claim percentage" and "fraudulent dollars percentage" for the 14 states for each NDC-quarter and then applied those average ratios to the total claims and total

Medicaid amounts paid for the remaining states by state, NDC and quarter. *Id.* ¶ 157. With respect to Medicare claims, Dr. Duggan first reviewed the claims processed by Medicare DMERCS under the DME benefit. He had array information that applied to more than 90 percent of these DME claims, and detailed in his report, he dropped those claims for which he was unable to replicate the allowed amount from the claim from the array documents. Thus, there was no need to extrapolate damages in connection with the DME claims. Thus, Dey cannot demonstrate any inappropriate extrapolation here. *Id.* ¶ 125.

Dey also contends that it is entitled to summary judgment on any claim paid on something other than the State's reimbursement methodology or even paid based on any element other than EAC, such as a FUL, MAC or U&C. The latter argument fails because under the "lower of" methodology used by the overwhelming number of States, the inflated AWPs and WACs are still being relied upon in the algorithm and therefore still influence the payment to be made for the drug by the government. The issue is not whether the claim was reimbursed with the FUL or MAC or U&C amount – the issue is whether a true or accurate AWP or WAC would have resulted in lower reimbursement for a specific NDC.

With respect to Medicare, Dey asserts that "there is no legal theory" on which it can "be held liable for damages caused by Roxane." Dey SJ Br. at 35-36. This argument misstates the United States' claim for damages based on the joint impact Dey and Roxane's reported AWPs had on Medicare reimbursement for ipratropium bromide.[11] The evidence in this case is more than sufficient to establish that Dey is a legal cause of the full injury to the Medicare program

[11]In light of the joint harm caused to the United States by Dey and Roxane's false AWPs for this drug, the United States intends to move to consolidate the two cases for trial.

which resulted from its reported AWPs, including where Dey's reported prices combined with other manufacturers' prices such as Roxane's to jointly harm Medicare.

Causation under the FCA generally involves application of common-law tort concepts, *see Parke-Davis*, 2003 WL 2048255, at *4, which "recognize that concurrent forces may bring about a single harm." *See, e.g., Shyface v. Secretary, Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (*citing Restatement (Second) of Torts* § 433 cmt. d); *Comdyne I, Inc. v. Corbin,* 908 F.2d 1142, 1151(3rd Cir. 1990) ("[W]here a harm is produced by concurrent acts, each act is the cause of the harm if it was a material element or 'substantial factor' in bringing the harm about") (internal citation omitted).

Medicare reimbursement was paid according to a common HCPCS code encompassing the products of different manufacturers of the same drug. Dey SOF ¶¶ 168-69. Therefore, Medicare's allowed reimbursement amount for ipratropium bromide was based on both Dey and Roxane's reported AWPs. *Id.*, ¶¶ 168-70. Because the allowed reimbursement amount often was set at the median of the generic AWPs, 42 C.F.R. § 405.517(c), the submission of false prices by multiple manufacturers at times increased the median AWP (thereby increasing reimbursement) even though any one manufacturer's AWP, viewed in isolation, had no effect on the median. US-D-SF ¶ 226. Dey has not even attempted to show that it was not a substantial factor in causing the harm Medicare suffered as a result of the joint impact of its and Roxane's false AWPs, nor has Dey attempted to show that this impact was unforeseeable. *See In re Polaroid Corp. Securities Litig.*, 134 F. Supp. 2d 176, 188 (D. Mass. 2001) (proximate cause shown where defendant was a "substantial factor in the sequence of responsible causation" and

the injury "was reasonably foreseeable or anticipated as a natural consequence") (internal citation omitted).[12]

Therefore, summary judgment as to damages should be denied.

G. Dey Has No Due Process Claim

Dey contends that the government's pre-intervention investigation of the fraudulent conduct at issue violated its due process rights and, consequently, the government should be barred from recovering the hundreds of millions of dollars in fraudulent overpayments as a result. Dey SJ Br. at 24-26. As set forth more fully in the United States' common brief, Dey's claim has no merit.

In response to this same argument by Dey previously, the Court concluded that "Dey [had] not produced any evidence that these extensions were improper, in bad faith, or prejudicial." *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 399 (D. Mass. 2007). The Court laid out the proper standard for finding a due process violation – a standard as to which Dey still falls short. For a due process violation when an action was timely filed, a defendant must show "that the government intentionally delayed to gain a tactical advantage and that actual prejudice resulted." *United States ex rel. Sarmont v. Target Corp.*, 2003 WL 22389119 *6 (N.D. Ill. Oct. 20, 2003) (citing *United States v. Marion*, 404 U.S. 307, 324 (1971)." The *Sarmont* court found no due process violation in connection with an FCA pre-intervention investigation of a similar duration (10 years). The *Sarmont* court correctly determined, as an initial matter, that the length of the investigation alone does not trigger a finding of bad faith. *Id*. at *5.

[12] Dey seeks summary judgment on Medicare damages for cromolyn sodium. The United States is not seeking any such damages. Nor is the United States seeking damages where Dey's price is not included in an array. Dey also seeks summary judgment for Medicaid damages for Texas, Ohio and Arizona. The United State is not seeking damages for those states.

Dey claims that the government used the length of the pre-investigation to tactical advantage, keeping the claims at issue secret and characterizing the statutorily-mandated investigation as "one-sided discovery." Again, the *Sarmont* court addressed similar arguments and concluded:

> The Court's own review of the record reveals several factors which appear to have contributed to the prolonged investigation . . . Target's counsel was heavily engaged in discussions with the U.S. Attorney's Office . . . Target credibly submits that its interaction with the U.S. Attorney's Office was nothing more than the typical negotiating (ultimately successful) for a declination of prosecution. In any event, the parties have presented nothing which suggests that the investigative delay in this case, while undeniably significant, was due to the bad faith of any party.

Id. at *6.

As in the *Sarmont* case, Dey was on full notice of the investigation and the *qui tam* in this matter. HHS-OIG served document subpoenas on Dey in 1997 and 2000, which Dey received and to which it partially responded.[13] Further, on October 24, 1997, the United States obtained a partial lift seal order, allowing it to disclose to Dey the substance of the allegations against Dey, met with Dey in the fall of 1998 about the allegations, and received in 2000 a 36-page joint "white paper" prepared by Dey and other manufacturers to the head of the DOJ Civil Division, entitled "Analysis of Why the United States Should Decline Intervention in United States Ex Rel. [Relator] v. [Defendants] (S.D. Fla.) (Under Seal). Any claim or intimation from Dey it was not

[13] As set forth in the United States' Memorandum in Opposition to Dey's Motion to Dismiss (MD# 3607), after relator filed suit under seal against Dey in Massachusetts in April 2000, alleging pricing fraud with respect to additional drugs, the United States Attorney's Office for the District of Massachusetts issued authorized investigative demands ("AIDs") for documents from Dey on or about August 25, 2000, October 16, 2001, and May 19, 2003. As with the OIG subpoenas, these demands sought pricing and marketing information.

on notice of the claims and/or not engaging the government about the allegations during the pre-intervention investigation in this case is patently untrue.

On the prejudice showing, a claim of prejudice must be "specific, concrete and supported by evidence." *United States v. Sowa*, 34 F.3d 447, 450 (7th Cir.1994). Dey's claim of bad faith and actual prejudice is all rhetoric; there is absolutely no evidence that the government intentionally delayed intervention in these cases to gain a tactical advantage, acted in bad faith or that any actual prejudice resulted from the pre-seal investigation. As it did previously, the Court should reject this argument.

H. Dey's Motion for Summary Judgment on The Government's Unjust Enrichment Claim Should be Denied

Dey argues that summary judgment should be granted upon the unjust enrichment claim because there is an adequate remedy at law and no evidence that Dey was enriched. Dey SJ Br. at 37-39. This Court previously held that the unjust enrichment claims against Dey did not relate back to relator's complaints. *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d at 398-401. The alternate remedy and relation back issues have been addressed in the common brief at Section IV, B. For the reasons explained below, Dey's remaining argument, that it was not enriched by its fraud, has no merit.

Dey's argument relies on the false premise that Dey's enrichment could only consist of the amount by which its sales or market share increased over the relevant period for the Subject Drugs.[14] Dey need not have increased its sales - numerically or relative to its competitors - in

[14] Dey's argument - that a flat or decreasing sales and market share proves Dey was not enriched by its fraud - may make sense in one hypothetical situation: if Dey were the only manufacturer of the Subject Drugs reporting inflated prices. That is not the case here.

order to have become enriched. Dey itself contends that Dey's competitors were also reporting prices with large spreads. *See*, *e.g.,* Dey SOF ¶¶ 67, 69, 153 (reflecting Dey's belief that the practice of reporting prices with large spreads was common in the industry). Market share did not necessarily reflect which products cost less, but rather which gave buyers more reimbursement via the spread. Therefore, while Dey's market share may reflect the scale of its fraud relative to that of its competitors, it does not disprove enrichment.[15] Nor does the fact that the providers were enriched: it is the United States' position that the providers *and* Dey were enriched.

Dey's marketing and training materials reflect Dey's belief that its spreads allowed it to sell more drugs than it would have without the spread. *See, e.g.,* US-D-SF ¶¶ 103 (training materials on reimbursement); 119 (marketing document touting the "reimbursement advantage" in sales of certain dose packages); and 122 (reflecting Dey's belief that it lost a sale because competitor's spread was larger). The evidence of Dey's enrichment lies in its earnings for the Subject Drugs, which it could not have realized had Dey reported accurate prices and denied its customers the benefit of the spread. US-D-SF ¶ 234. Dey was a for-profit corporation engaged in the business of selling the Subject Drugs during the relevant period, and sell them it did, earning sizeable profits it could not have earned had it not engaged in fraud. While there is no doubt Dey was enriched by its fraudulent scheme, the question of *how much* is, at the very least, a question of fact best left for trial.

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[15] Even under a market share theory, there is evidence Dey was enriched. For example, Dey dominated the Medicaid-reimbursed ipratropium bromide market for much of the relevant period, growing from 37.5% in the first quarter of 1998 to over 70% of the market in 2000. US-D-SF ¶ 233. From 1998 through 2003, Dey's average market share was 55.6%. *Id.* This evidence of market share creates a question of fact as to whether Dey was enriched.

IV. CONCLUSION

For all of the foregoing reasons, the United States respectfully requests that the Court grant the United States' motion for partial summary judgment and deny Dey's motion for partial summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF UNITED STATES' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO THE DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT"

to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
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Assistant U.S. Attorney

Dated: July 24, 2009

CERTIFICATION

The undersigned hereby certifies pursuant to LR 7.1(A) that counsel have conferred and have been unable to resolve or narrow the issues.

/s/ George B. Henderson, II
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